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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/269,874	08/02/1999	HERMANN BUJARD	402162000200	1745
24353	7590	03/26/2004	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP			DUFFY, PATRICIA ANN	
200 MIDDLEFIELD RD			ART UNIT	
SUITE 200			PAPER NUMBER	
MENLO PARK, CA 94025			1645	

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/269,874

**Applicant(s)**

BUJARD ET AL.

**Examiner**

Patricia A. Duffy

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 42-46, 49-100 is/are pending in the application.
- 4a) Of the above claim(s) 50-53 and 58-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42-46, 49, 54-57 and 83-100 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 42-46, 49-100 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### RESPONSE TO AMENDMENT

The amendment filed 13-23-03 has been entered into the record. Claims 1-41, 47, 48 and 53 have been cancelled. Claims 50-52 and 58-82 are withdrawn from consideration. Claims 42-46, 49, 54-57 and 83-100 are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

### *Drawings*

The drawings were received on 12-23-03. These drawings are approved.

### *Election/Restrictions*

This application contains claims 50-52 and 58-82 are drawn to an invention nonelected with traverse in the response to the lack of unity requirement in the Response filed 7-10-01. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### *Rejections Objections/Withdrawn*

The objection to claims 47, 48 and 49 under 37CFR 1.75( c) is withdrawn based on the amendments or cancellation of the recited claims.

The rejection of claims 47, 48 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn based on cancellation of the claims. This rejection is not applicable to the newly presented claims.

The rejection of claims 42-49 and 53-57 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn based on Applicants presentation of sufficient evidence of other *Plasmodium* MSP-1

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nucleotide sequences were known to the art at the time of filing and amendments to the claims.

The rejection of claim 53 under 35 USC 112, first paragraph is withdrawn based on cancellation of the claim.

The rejection of claims 42-49 and 53-57 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as drawn to the issue of "complete" only is withdrawn in view of Applicants' amendment to the claims.

The rejection of claims 42-48 and 54 under 35 USC 102(b) as being anticipated or under 35 USC 103(s) as being unpatentable over Holder et al (Nature, 317:270-273, 1985) is withdrawn in view of Applicants' amendments to the claims.

#### *Rejections Maintained*

Claims 42-46, 49, 54-57 and 83-100 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention as new matter is maintained for reasons made of record in the previous office action and newly applied across newly presented claims 83-100.

As to claims 42-46, 49, 54-57 and 83-100, Applicants indicate that the amendment to recite "corresponding" obviates this rejection. This is not persuasive, the claims must convey the concept of the corresponding naturally occurring gene from which it was derived (see specification page 8, second full paragraph). The claims still recite "a" as in comparison of any native sequence with the AT reduced sequence. The claims need to recite less than *the* AT content of *the* corresponding naturally occurring nucleotide sequence encoding *the* gp190/MSP-1 protein.

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The rejection of claims 42-46, 49, 54-57 and 83-100 stand under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons made of record in the previous office action of record as set forth below.

As to all the claims, the claims are still indefinite because it compares two sequences wherein the naturally occurring sequence is not structurally defined and recites "a" as in any naturally occurring form and not the wild type/naturally occurring form from which it is derived. The claim still appears to not compare any wild type sequence and with a derived sequence, wherein the naturally occurring nucleotide sequence is not defined as the wild type from which it is derived. As such, one skilled in the art would not be readily apprised to the metes and bounds of the AT modified nucleotide sequence nor be able to readily ascertain whether or not they were infringing.

As to claims 46, 87, 88, 91, 96, 97, 98, 99, 100, the claims are still indefinite because the independent claims recite two different nucleotide sequences and because the dependent claims still recite "the nucleotide sequence" and it is still unclear which nucleotide sequence is being referenced, because at least two different nucleotide sequences are set forth in the independent claims. Applicants may wish to consider crafting the dependent claims to recite "the expressed nucleotide sequence" or "the naturally occurring (wild type) nucleotide sequence" to clearly delineate which sequence is being referenced.

#### *New Objections/Rejections Based on Amendment*

##### *Specification*

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the specification lacks antecedent basis for the amended language of the claims "having an approximate weight of 190 kD."

*Claim Rejections - 35 USC § 112*

Claims 42-46, 49, 54-57 and 83-100 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims now recite the concept of a gp190/merozoite surface protein -1 (MSP-1) protein of a *Plasmodium* having an approximate weight of 190 kD. This term lacks basis in the specification as filed because the main surface protein of the merozoite of the genus *Plasmodium* is described using a specific molecular weight range of 190-220 kD glycoprotein (see page 2, second full paragraph). This passage does not support the term "approximate" because the term approximate provides for latitude below 190 kD which has no written description in terms of the genus. The only other passage that discusses the molecular weight of 190 kD is page 6, last paragraph which discusses an antigen precursor from a particular strain of *Plasmodium falciparum* (FCB1) having a precursor molecular weight of 185-195 kD. Therefore, this teaching is limited to a particular species and does not provide for conception of latitude of a molecular weight below 190 kD for the genus. As such, the recitation of "... having an approximate weight of 190 kD.." therefore lacks conception by way of written description in the specification as filed.

*Status of Claims*

All claims under examination stand rejected.

*Allowable Subject Matter*

The following prototype independent claim (corresponding to claim 42 of record) would resolve many 35 USC 112, 1st paragraph issues presented supra.

It is set forth for Applicants consideration.

Claim A. A method for producing a merozoite surface protein - 1 (MSP-1) of a *Plasmodium* having a molecular weight of 190-220 kD that has both a signal peptide and an attachment signal, comprising expressing a nucleotide sequence encoding the MSP-1 in a single expression vector, wherein the adenine and thymine (AT) content of the expressed nucleotide sequence encoding the MSP-1 is less than the AT content of the corresponding naturally occurring nucleotide sequence encoding the MSP-1.

#### *Relevant Art*

Chen et al US Patent No. 6,593,463 B1 issued July 15, 2003 teaches expression of modified MSP-1 sequences.

Chen et al US 2002/0144299 A1 published October 3, 2002 teaches expression of modified MSP-1 sequences.

#### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP S 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-F 6:30 pm - 3:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Smith Lynette can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

*Pat A. Duffy*  
Patricia A. Duffy

Primary Examiner

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